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VIA ECF

Hon. Steven Ian Locke
United States Magistrate Judge
United States District Court
Eastern District of New York
610 Federal Plaza
Central Islip, NY 11722

Re: United States v. Lloyd Landsman
Docket No.: 17-cr-00653

Dear Hon. Locke:

Please find enclosed herein Objections to Paragraphs 1 through 11 of the Presentence Investigation Report prepared June 29, 2018 and the Sentence Recommendation, entitled Comments. Please consider the within Objections.

Charges and Convictions:

Para. 1: On December 5, 2017, the Defendant plead guilty before the Hon. Steven Locke to a single count Information. He allocuted to the following:

From May, 2013 until June, 2016, in the Eastern District of New York, at my office in Smithtown, New York, I knowingly and intentionally received from Canada and Great Britain and delivered to my patients for pay a non FDA approved injectable botulinum toxin Drug, Botox, that was misbranded because the label did not bear the symbol "Rx only" and required black box warnings.

Thus, the Defendant's plea was limited to only receiving and delivering non FDA approved, misbranded (misabeled) botulinum toxin or Botox. No other drugs were addressed or considered within the plea.

Para. 2: No objection.

Para. 3: No objection.

The Offense Conduct:

- Para. 4: There is a significant difference between Botox and dermal fillers. The FDA characterizes Botox as a drug, whereas dermal fillers are characterized as medical devices. Nowhere within Dr. Landsman's plea was there any admission or acknowledgment of the improper or illegal utilization of dermal fillers. Further, while Botox as a drug requires black box warnings, dermal fillers do not. A review of your Para. 4 reveals several significant errors in the characterization of both Botox and dermal fillers. Botox, a drug, is a different class of compounds than that of dermal fillers. It is a neurotoxin which causes temporary paralysis of skeletal muscle, reducing movement and thus, reducing lines. Dermal fillers are an entirely different class of products which are not pharmacologically active, they are bio compatible and are used to provide volume and contour improvements in mostly the facial area. Neither Botox or dermal fillers, if properly administered, can cause injury to a patient. Expired products would merely lose their efficacy, but in no way would be harmful to the patient.
- Para. 5: The last sentence of Para. 5 should state, "he also rents small spaces for the administration of Botox, dermal fillers and consultations at several spas and salons".
- Para. 6: Any discussion as to the activities of Medical Device King or Pharmacy Plus Supplies, Ltd. should be stricken within Para. 6 in that they are completely irrelevant to the matter before the Court. While it is accurate that in 2011 and 2013 Dr. Landsman did receive items from Medical Device King/Pharmalogical, he along with many other physicians, was unaware that this Great Neck drug wholesaler was under investigation which resulted in counterfeit drug and fraud charges being leveled against the President and Vice President of the above entities. At the end of June, 2013, the FDA sent warning letters to approximately 800 medical practices throughout the United States concerning their business exchanges with a black market medication wholesaler called Medical Device King/Pharmalogical. Apparently, the entities were selling counterfeit cancer medications and other drugs and medical devices to many practicing physicians throughout the United States. While Dr. Landsman purchased drugs and medical devices from this entity from June, 2011 through 2013, he had no knowledge that the entities were trafficking in misbranded and counterfeit prescription drugs. Although you mention Dr. Landsman's dealings with Medical Device King/Pharmalogical, at no time do you indicate that Dr. Landsman, like many other physicians throughout the United States, had no knowledge of Medical Device King/Pharmalogical's deception.
- Para. 7: Within Para. 7, in discussing the two vials of Botox which were seized by customs at JFK Airport International Mail Facility on January 28, 2016, you utilized the term "adulterated and unapproved". This characterization is not supported by the

evidence. Since the Botox remained within the facility from January 28, 2016 until after FDA investigation on February 26, 2016, there would be no way of determining if the two vials of Botox seized were adulterated. The seizure of the two vials of Botox was predicated upon their misbranding (mislabeling) in that the shipment failed to possess black box warnings. The lack of this piece of paper is in no way determinative of whether the two vials of Botox were adulterated or not.

Para. 8: Para. 8 should be deleted in its entirety in that it once again refers to the activities of Medical Device King/Pharmalogical and not any wrong doing by Dr. Landsman. As previously discussed, many physicians utilized Medical Device King/Pharmalogical, a Great Neck drug wholesaler, to acquire medical products. Unbeknownst to these physicians, the entity was providing misbranded and, at times, counterfeit prescription drugs. Dr. Landsman and all of his cohorts had no knowledge or notice of this deception. Immediately upon learning of Medical Device King/Pharmalogical's transgressions, Dr. Landsman immediately stopped ordering any product from the entity.

Para. 9: Significant portions of Para. 9 should either be stricken or corrected. Reference is made to the fact that Dawn Wagner provided the FDA-OCI Agent with one bottle of Botox which the investigator confirmed as "foreign unapproved product". The bottle was not a foreign unapproved product, but one mislabeled bottle of Botox.

During the investigator's visit, he affixed a business card to the bottle and instructed Ms. Wagner to contact him as soon as possible. Reference is made to the fact that "the investigator left several more messages for the Defendant through May and June, 2016, with no response from the Defendant. It must be noted that Dr. Landsman's father-in-law was suffering from Stage 7 Alzheimers and being cared for solely by his mother-in-law at that time. He was actively involved and tending to his mother-in-law who was suffering from severe depression up until May, 2016 when she ultimately committed suicide. From May 15, 2016 through June, 2016, Dr. Landsman barely attended his practice during that time as he was the person holding the family together and caring for his father-in-law.

Towards the latter portion of the Paragraph, Pharmalogical's purchases are once again mentioned in an improper and prejudicial manner as to Dr. Landsman. As previously indicated, Dr. Landsman possessed no knowledge of Pharmalogical's transgressions at the time he purchased products from them.

The paragraph also speaks of a time frame from January, 2012 to February, 2016 wherein it is disclosed that Dr. Landsman ordered \$268,011.00 in foreign unapproved Botox and a number of dermal fillers from Medica Depot. This sentence should be stricken in that it is wholly irrelevant to the issues at hand. Dr. Landsman is charged with obtaining mislabeled Botox with no reference to dermal fillers.

The paragraph also indicates that between March 10, 2016 and July 8, 2016, the Defendant ordered \$13,485.00 worth of Botox and assorted dermal fillers. This statement is inaccurate in that as of January 19, 2016, Dr. Landsman ceased ordering Botox from Medica Depot. (A copy of his last order is annexed hereto as Exhibit A).

Lastly, the statement that between November 18, 2010 and July 8, 2016, that Defendant ordered \$317,477.11 in foreign unapproved dermal fillers is not only erroneous, but completely irrelevant. The purchase of Botox and dermal fillers cannot be lumped together in assessing Dr. Landsman's culpability. In addition thereto, a distinction must be made between the purchases with Medical Device King/Pharmalogical and those of Medica Depot. The figure of \$317,477.11 is inflammatory, prejudicial and inaccurate.

Para. 10: The first sentence within Paragraph 10 is inaccurate in that Dr. Landsman never purchased unapproved drugs. The only drug that Dr. Landsman purchased which was mislabeled was Botox. The second sentence within Paragraph 10 is also inaccurate and confusing. Once again, it references the improper and illegal activities of Medical Device King/Pharmalogical and not that of Dr. Landsman. The fact that Dr. Landsman admitted ordering Botox and dermal fillers from Medical Device King/Pharmalogical in 2010 and 2011 is wholly irrelevant and unnecessarily inflammatory. Dr. Landsman had no culpability as to the actions of the principals of Medical Device King/Pharmalogical.

Para. 11: In Para. 11, dermal fillers are erroneously characterized as drugs.

U.S. Probation Dept. Sentence Recommendation:

Comments:

The first sentence within your comments is inaccurate in that the Defendant was convicted of purchasing and receiving misbranded/mislabeled Botox and no other drugs. References covering the time frame from 2010 through 2014 are not only irrelevant, but are misleading in that they fail to disclose the activities of Medical Device King/Pharmalogical.

Lastly, within the first paragraph it states, "agents went to the defendant's practice in 2013 and again in 2016 to discuss the purchase of unapproved dermal fillers". Agents went to Dr. Landsman's practice on these dates to discuss the purchase and acquisition of Botox - not dermal fillers.

In the fourth paragraph of your comments, you find it "somewhat troublesome that the defendant acknowledged that he prescribes himself anti-depressants as needed". The paragraph fails to state that Dr. Landsman had previously treated with a psychopharmacologist, Dr. Tarin Fishman, who prior to retiring from the practice, prescribed Dr. Landsman Effexor, 125 mg. as an anti-

depressant. After his arrest, Dr. Landsman also saw another psychiatrist who prescribed the same medication for a brief period of time until Dr. Landsman's depression abated.

In the eighth paragraph of your comments, you indicate that the instant offense is viewed as very serious regarding the risks to the health and appearance of Dr. Landsman's patients. Yet, the use of Botox and dermal fillers as acquired by Dr. Landsman provide little, if any, risk to his patients. Neither Botox nor dermal fillers provide any level of potential danger to the patients. The Botox utilized was not counterfeit or adulterated, but mislabeled as a result of its importation from Canada. Thus, the administration of the Botox provided no serious health risk to any of Dr. Landsman's patients.

As previously requested, upon receipt and review of the within, please contact me to further discuss the issues raised above.

Very truly yours,



Lawrence V. Carra

LVC:ag

Enc.

cc: P.O. Lisa Langone (Via e-mail to: Lisa_Langone@nyep.uscourts.gov)